



## **FORM OF INFORMATION AND INFORMED WRITTEN CONSENT**

Order of 8 of Julio 2009 (BOJA nº 152 of date August 6) for which instructions are dictated to the Centers of the Sanitary Public System of Andalusia, in relation to the procedure of Informed Consent.

### **1. DOCUMENT OF INFORMATION FOR LUMBAR PUNCTURE**

This document serves so that you, or who represents it, give its consent for this intervention. That means that it authorizes us to carry out it.

You can to retire this consent when you want it. To sign it doesn't force you to be made the intervention. Of their rejection he/she won't be derived any adverse consequence regarding the quality of the rest of the received attention. Before signing, it is important that you read the following information slowly.

Tell us if he/she has some doubt or he/she needs more information. We will assist him/her with a lot of pleasure.

#### **1.1 WHAT YOU SHOULD KNOW:**

##### **ON WHAT IT CONSISTS?. FOR WHAT REASON IT SERVES?:**

It is a simple and safe procedure to draw a sample of cerebrospinal fluid (CSF) with a needle from the lumbar spine.

CFS is a fluid that normally surrounds the brain and the spinal cord. Due to this, many meningeal, cord and cerebral diseases lead to changes in the composition of CSF. The analysis of CFS is essential for the diagnosis of a lot of central nervous system disorders. Moreover, lumbar puncture is also used for measuring the CFS pressure, giving medications or injecting X-ray contrasts. Finally, CSF can be drained by lumbar puncture as a part of the therapy of some diseases.

##### **HOW IS IT CARRIED OUT?**

It is carried out puncturing with a fine needle in the back, at level of the lumbar spine, in the space that there is between two vertebrae, after disinfecting the area and under sterile conditions.

The patient should be placed in the position to increase the spaces between the vertebrae:

1.- in the bed, put to bed of side, with the knees in flexion all the possible one, trying to play them with the head, and the neck in flexion trying to play the chest with the chin (foetal position).

or 2.- sit down: with the neck in flexion all that you can

The fluid is withdrawn through a thin, hollow needle from the low back. The needle is introduced into the space existing between two vertebrae.



### **WHAT EFFECTS IT WILL PRODUCE TO YOU?**

In general, you will notice the nuisances characteristic of a jab. The injection of the anesthesia already supposes a jab, and is only used occasionally.

You can feel certain pain during the puncture and even cramps but it should be about the stillest thing being possible.

It is possible that it is needed more than a jab to be able to locate and to extract the liquid.

### **IN WHAT IT WILL BENEFIT TO YOU?**

The analysis of the CSF can help to diagnose your illness and therefore to carry out a correct treatment.

### **OTHER AVAILABLE ALTERNATIVES IN YOUR CASE?**

The lumbar punción is the simplest way to obtain CSF to analyze it and to be able to arrive to the diagnosis of certain illnesses

### **WHAT RISKS DOES IT HAVE?**

Any medical performance has risks. Most of the times the risks are not materialized, and the intervention doesn't produce damages or secondary undesirable effects. But sometimes this is not possible. For that reason it is important that you know the risks that it can appear in this process or intervention.

#### **THE MOST FREQUENT:**

- The most common thing is that headache appears for the decrease of pressure after the extraction of liquid. It can accompany of you nausea, vomits and vertigo. Bed resting and drinking lots of water after the puncture prevent headache. At any case, if you feel headache you can ask the nurse for an analgesic.
- Radiculalgia: pain to touch a root, is habitually transitory.
- Lumbar pain: frequently temporary.

#### **THE MOST SERIOUS:**

- The infections (meningitis, espondylitis, cellulitis) are rare when the puncture is carried out under strict sterile conditions.
- Local Hematomas in the puncture site are quite uncommon.
- Hemorrhages (epidural, subdural and subarachnoid): as exceptional events, intracranial hematomas due to low CSF pressure and transtentorial herniation can follow lumbar puncture. Transtentorial herniation is a life-threatening complication which can emerge in patients with intracranial diseases, like large masses. These disorders have been reasonably ruled out in your case by the medical history, the physical examination and the image studies.
- pneumoencephalo: entrance of air in the subarachnoid system.
- Lesion in spinal marrow: although the puncture is carried out where there is no longer marrow, only liquid and nervous roots this complication is exceptional.
- Lesion from some root nervous.
- Allergic reaction to the anesthesia.

#### THOSE DERIVED OF YOUR PROBLEMS OF HEALTH:

- If you have blood disorders or you are under anticoagulant therapy, there will be more risk of having bled.
- If you suffer chronic illnesses as heart failure, chronic obstructive pulmonary disease (COPD), diabetes, chest angina, arterial hypertension, etc, the risk can be bigger.

Due to your own characteristics, there are the following additional risks:

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#### **SPECIAL SITUATIONS THAT SHOULD BE KEPT IN MIND**

If you have some medical problem related with the clotting of the blood or taking some medication that affects to the same one, it can be necessary to retard this procedure until improving the clotting.

#### **OTHER INFORMATIONS OF INTEREST (to consider for the professional)**

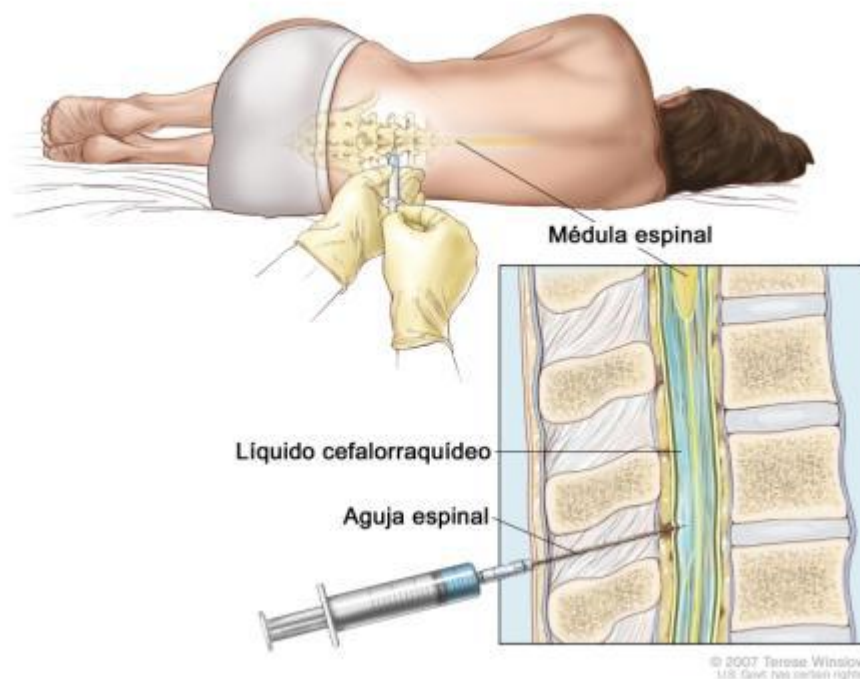
To diminish the possibility that headache appears after the puncture, it is recommended that you keep rest in bed and take abundant liquids during the following hours to the procedure. In all ways, if headache appeared, you can request the nurse an analgesic drug.

#### **OTHER QUESTIONS FOR THOSE THAT WE REQUEST YOUR CONSENT**

- Sometimes, during the intervention, accidental discoveries take place. They can force to have to modify the form of to make the intervention and to not use variants of the same one contemplated initially.
- It is sometimes necessary to take biological samples to study their case well. They can be conserved and used later on to carry out investigations related with the illness that you suffer. They were not used directly for commercial ends. If they will be used for other different ends you would be requested the expressed consent later on for it. If he/she doesn't give their consent to be used in investigation, the samples will be destroyed once they stop to be useful to document their case, according to the norms of the center. Anyway, it will be protected the confidentiality appropriately in all moment.
- It can also be necessary to take images, as pictures or videos. They are good to document the case well. They can also be used for educational ends of diffusion of the scientific knowledge. Anyway they will be used if you give their authorization. Their identity will always be preserved in a confidential way.

## 1.2. EXPLANATORY IMAGES:

In this space they will be able to insert with character explanatory optional images, anatomical outlines, pictograms etc. that they facilitate and allow to explain in a simpler way the information to the patient.



## 2. INFORMED WRITTEN CONSENT

### 2.1. DATA OF THE / OF THE PATIENT AND DE THEIR REPRESENTATIVE (ONLY IN CASE OF INABILITY OF THE / OF THE PATIENT)

Patient name&lastname

Document of identity/Passport number

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Deputy name&lastname

Document of identity/Passport number

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## 2.2. PROFESSIONALS THAT INTERVENE IN THE PROCESS OF INFORMATION AND/OR CONSENT

Name&lastname	Date	Signature
_____	_____	_____
Name&lastname	Date	Signature
_____	_____	_____
Name&lastname	Date	Signature
_____	_____	_____
Name&lastname	Date	Signature
_____	_____	_____

## 2.3. CONSENT

I, Mr / Mrs/Miss \_\_\_\_\_ manifesto that I am according with the intervention that I have been proposed. I have read and understood the previous information. I have been able to ask and to clarify all my doubts. For that reason I have taken conscious and freely the decision of authorizing it. I also know that I can retire my consent when it estimates it opportune.

☐ Yes ☐ No I authorize to that are carried out the opportune performances, including modifications in the form of carrying out the intervention, to avoid the dangers or potential damages for the life or the health that could arise in the course of the intervention.

☐ Yes ☐ No I authorize the conservation and later use of my biological samples directly for related investigation with the illness that I suffer.

☐ Yes ☐ No I authorize that, in case my biological samples will be used in other different investigations, the investigators contact me to request me consent.

☐ Yes ☐ No I authorize the use of images with educational ends or of diffusion of the scientific knowledge.

NOTE: Mark you with a cross.

Córdoba (Spain), month ...../day...../Year 201\_\_

.....  
Physician signature

.....  
Patient/deputy signature  
(only if patient's inability)

#### **2.4. REJECT OF THE INTERVENTION**

I, Mr / Mrs / Miss, I don't authorize to the realization of this intervention. I assume the consequences that of they can be derived for the health or the life.

Córdoba (Spain), month ...../day...../Year 201\_\_

.....  
Physician signature

.....  
Patient/deputy signature  
(only if patient's inability)

#### **2.5. CONSENT REVOCATION**

I, Mr / Mrs / Miss, in a free and conscious way I have decided to retire the consent for performing this intervention. I assume the consequences that of they can be derived for the health or the life.

Córdoba (Spain), month ...../day...../Year 201\_\_

Physician name

Patient/deputy name

.....  
Physician signature

.....  
Patient/deputy signature  
(only if patient's inability)